

Remarks

By the foregoing amendments, Applicants have amended the international application to update the priority information as required by 37 C.F.R. § 1.78, and to place the claims into proper format for U.S. practice. Support for the amendments to claims 3-9, 11-13, 17, 22-25, 27, 29 and 30, and for new claims 32-75, may be found throughout the specification and claims as originally filed. Accordingly, the foregoing amendments add no new matter, and their entry and consideration are respectfully requested. Upon entry of the foregoing amendments, claims 1-17 and 20-75 are pending in the application, with claims 1, 16, 17, 20 and 28 being the independent claims.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

Date: June 26, 2002
1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005
(202) 371-2600

Version with markings to show changes made

In the Specification:

In the specification at page 1, after the title, please delete the first two paragraphs (the Cross Reference section, inserted by the Preliminary Amendment filed on December 21, 2001), and substitute therefor the following:

--
CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of [U.S. Appl. No. _____ (Atty. Docket No. 0623.0730001/EKS/BJD)] U.S. Application No. 10/019,153, filed on December 21, 2001 (now abandoned), which is the U.S. National Phase of International Application No. PCT/GB00/02459, filed internationally on June 23, 2000, which was published in the English language under PCT Article 21(2) as WO 01/00855 on January 4, 2001, which claims the benefit of U.S. Provisional Application No. 60/147,819, filed August 10, 1999, and which claims priority to GB Application No. 9914733.2, filed June 23, 1999, the disclosures of all of which are incorporated herein by reference in their entireties. --

In the Claims:

- (a) Claims 18 and 19 are cancelled, without prejudice or disclaimer.
- (b) Claims 3-9, 11-13, 17, 22-25, 27, 29 and 30 are sought to be amended as follows:

3. (Once amended) A process as claimed in claim 1 [or claim 2] wherein the lysozyme fusion partner is expressed at more than 5g/l in the milk of transgenic animals and is stable with carboxy terminal extensions.

4. (Once amended) A process as claimed in claim 3 wherein the lysozyme fusion partner is from a placental [mammal, eg humans, cattle, sheep, goats, rabbits and rats.] mammal.

5. (Once amended) A process as claimed in [any one of claims 1 to 4] claim 1, wherein the peptide is from 3 to [110, preferably 3 to 100] 110 amino acids in length.

6. (Once amended) A process as claimed in [any one of claims 1 to 5] claim 1, wherein the peptide is one which requires post-translational modification in order to be biologically active, or to improve *in vivo* half [life, for example α -amidation.] life.

7. (Once amended) A process as claimed in claim 6 wherein the peptide is selected from the group consisting of calcitonin, parathyroid hormone, glucagon, glucagon-like-peptide-1, a peptide with anti-microbial [activity or a member of the general classes of peptide: magainins, histatins, protegrins and clavainins.] activity, a magainin, a histatin, a protegrin and a clavainin.

8. (Once amended) A process as claimed in [any one of claims 1 to 7] claim 1, wherein the lysozyme fusion partner [also includes] comprises a carboxy-terminus extension [sequence,] sequence which serves as a linker between the lysozyme fusion partner and the peptide.

9. (Once amended) A process as claimed in claim 8 wherein the linker sequence is at least [10, 15 or preferably at least 20] 10 amino acids in length.

11. (Once amended) A process as claimed in [any one of claims 1 to 10] claim 1, wherein the fusion partner protein [also] comprises a cleavage site between the fusion partner protein and peptide.

12. (Once amended) A process as claimed in claim 11 wherein the cleavage site is one which is [cleaved by chemical or enzymatic means] capable of being chemically or enzymatically cleaved.

13. (Once amended) A process as claimed in claim 12 wherein the cleavage site [includes] comprises a methionine residue and [cyanogen bromide is used as the cleavage reagent.] wherein said cleavage site is capable of being cleaved by cyanogen bromide.

17. (Once amended) A fusion protein comprising a fusion partner protein [and a peptide joined by means of] joined to a peptide by a flexible linker having the sequence (gly-gly-gly-gly-ser)₃.

22. (Once amended) A DNA molecule as claimed in [claim 21 which includes a promoter, preferably one which drives expression of a protein which is naturally found in the milk of a mammal.] claim 21, wherein said DNA molecule comprises a promoter.

23. (Once amended) A DNA molecule as claimed in claim 21 [or claim 22] which includes a protein leader sequence.

24. (Once amended) A DNA molecule as claimed in [any one of claims 20 to 23] claim 20 which further comprises a sequence encoding a linker sequence [as defined in any one of claims 8 to 10.] which serves as a linker between the lysozyme fusion partner and the peptide.

25. (Once amended) A DNA molecule as claimed in [any one of claims 20 to 24] claim 20, which further comprises a sequence encoding a cleavage site [as defined in any one of claims 11 to 15.] between said fusion partner protein and said peptide.

27. (Once amended) A host cell transformed with a vector as defined in [claim 26, preferably a mammalian cell.] claim 26.

29. (Once amended) A transgenic mammal as claimed in [claim 28 which is] claim 28, wherein said mammal is selected from the group consisting of a cow, a sheep, a goat, a rabbit, a mouse [or] and a pig.

30. (Once amended) A composition comprising [a] the fusion protein [as defined in any one of claims 16 to 19.] of claim 16 or claim 17.

(c) New claims 32-75 are sought to be entered.